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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): BODINE, Peter Van Nest et al. Examiner: Not yet known

Serial No.: 10/642,503 Group Art Unit: Not yet known

Filed: August 18, 2003

Title: BMP-2 ESTROGEN RESPONSIVE ELEMENT AND METHODS OF USING THE SAME

Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

Sir:

INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 C.F.R. §§1.56, 1.97 and 1.98, this Information Disclosure Statement includes Form PTO-1449:

1. ☒ listing documents including patents, publications and other information for consideration by the Examiner, however, since the subject application was filed after June 30, 2003, copies of United States patents, and/or United States patent applications, and/or United States patent application publications are not included in this information disclosure statement; and/or
2. ☐ listing documents including patents, publications and other information that have been previously cited or submitted to the Patent Office in prior application U.S. Serial No. _____, filed _____ which is properly identified and relied on for an earlier effective filing date under 35 U.S.C. 120 for consideration by the Examiner; however, in accordance with 37 C.F.R. 1.98(d), copies of such documents are not included in this information disclosure statement; and/or
3. ☐ listing documents including patents, publications, and other information for consideration by the Examiner, copies of which are included with this information disclosure statement;

4. ☐ listing other information for the Examiner's consideration which was cited in a communication from a foreign patent office in a counterpart foreign application, a copy of which is included with this information disclosure statement.

The information herein cited is only in fulfillment of Applicant(s) duty of candor in disclosing all information brought to Applicant(s) attention. This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or constitute "prior art". If it should be determined that any of the listed documents do not constitute "prior art" under United States law, Applicant(s) reserve the right to present to the office the relevant facts and law regarding the appropriate status of such documents.

Applicant(s) further reserve(s) the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

In accordance with MPEP Sections 609 and 707.05(b), it is requested that each and every document cited (including any cited in applicant's specification which is not repeated on the attached Form PTO-1449) be given thorough consideration and that it be cited of record in the prosecution history of the present application by initialing on Form PTO-1449. Such initialing is requested even if the Examiner does not consider it to be prior art for any reason, or even if the Examiner does not believe that the guidelines for citation have been fully complied with. This is requested so that each document becomes listed on the face of the patent issuing on the present application and is evidence that the Examiner has considered the document.

This Information Disclosure Statement is being filed:

I) ☒ Within three (3) months of filing the subject Application or entry of the subject Application into the national stage or before mailing of the first Office Action on the merits of the subject Application or a request for continued examination thereof, whichever event occurs last pursuant to of 37 C.F.R §1.97 (b); or

II) ☐ After the period specified in (I) but before the mailing date of either a final Official Action under 37 C.F.R §1.113 or a notice of allowance under 37 C.F.R §1.311 whichever occurs first and;

1. ☐ the undersigned hereby states that each item of information listed on the Form PTO-1449 was either (i) cited in a communication from a foreign patent office in a counterpart foreign application not more than three (3) months prior to

the filing of this Information Disclosure Statement or (ii) not cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned after making reasonable inquiry, not known to any individual designated in §1.56(c) more than three (3) months prior to the filing of this information disclosure statement; or

2. ☐ the undersigned hereby authorizes the Patent Office to charge the fee in the amount of \$180.00 under 37 C.F.R §1.17 (p) to Deposit Account 05-0649.

III) ☐ After the period in (I) and (II) but before the payment of the issue fee and,

1. The undersigned hereby states:

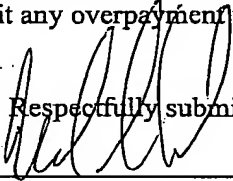
a) ☐ that each item of information cited on the form PTO-1449 was cited in a communication from a foreign Patent Office in a counterpart foreign application not more than three (3) months prior to the filing of this Information Disclosure Statement; or

b) ☐ that no items of information contained in Form PTO-1449 was cited in a communication from a foreign patent office in a counterpart foreign application, and to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in this Information Disclosure Statement was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement; and

2. ☐ The undersigned hereby authorizes the Patent Office to charge the Petition fee in the Amount of \$180.00 under 37 C.F.R §1.17 (p) to Deposit Account 05-0649.

APPLICANTS: BODINE, Peter Van Nest et al.
SERIAL NO.: 10/642,503
FILED: August 18, 2003
Page 4

Except for issue fees payable under 37 C.F.R. §1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. §§1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account No. 05-0649.


Respectfully submitted,

Mark S. Cohen
Attorney for Applicant(s)
Registration No. 42,425

Dated: July 25, 2004

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~~JUL 30 2002~~

Filing Date	August 18, 2003
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First Named Inventor	BODINE, Peter V
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Group Art Unit	Not yet known
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Examiner Name	Not yet known
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Attorney Docket Number	P-4921-US
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet	1	of	4
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U.S. PATENT DOCUMENTS

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FOREIGN PATENT DOCUMENTS

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¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

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				Application Number	10/642,503
				Filing Date	August 18, 2003
				First Named Inventor	BODINE, Peter Van Nest
				Group Art Unit	Not yet known
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Sheet	2	of	4		

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (where appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	E	Black, LJ et al., (1994) Raloxifene (LY139481 HCl) Prevents Bone Loss and Reduces Serum Cholesterol without Causing Uterine Hypertrophy in Ovariectomized rats. J. Clin. Invest. 93(1): 63-69.	<input type="checkbox"/>
	F	Chowdhury, J. R. et al. (1991) Long-Term Improvement of Hypercholesterolemia After ex Vivo Gene Therapy in LDLR-Deficient Rabbits. Science 254:1802-1805.	<input type="checkbox"/>
	G	Clemett D. et al., (2000) Raloxifene – Review of its Use in Postmenopausal Osteoporosis. Drugs 60(2):379-411	<input type="checkbox"/>
	H	Gazit D. et al., (1999) Recombinant TGF-β1 Stimulates Bone Marrow Osteoprogenitor Cell Activity and Bone Matrix Synthesis in Osteopenic, Old Male Mice. J. Cell Biochem. 73: 379-389.	<input type="checkbox"/>
	I	Goswami PC et al., (1997) A polymerase chain reaction assay for simultaneous detection and quantitation of proto-oncogene and GAPD mRNAs in different cell growth rates. Cell Prolif. 30:271-282.	<input type="checkbox"/>
	J	Hanada K. et al., (1997) Stimulatory Effects of Basic Fibroblast Growth Factor and Bone Morphogenetic Protein-2 on Osteogenic Differentiation of Rat Bone marrow-Derived Mesenchymal Stem Cells. J. Bone Miner. Res 12:1606-1614.	<input type="checkbox"/>
	K	Katagiri T et al., (1990) The non-osteogenic mouse pluripotent cell line, C3H10T1/2, is induced to differentiate into osteoblastic cells by recombinant human bone morphogenetic protein-2. Biochem Biophys Res Commun. 172:295-299	<input type="checkbox"/>
	L	Kay, M. A. et al. (1992) Hepatic Gene Therapy: Persistent Expression of Human-α1-Antitrypsin in Mice after Direct Gene Delivery In Vivo. Human Gene Therapy 3:641-647.	<input type="checkbox"/>
	M	Oreffo R et al. (1999) Expression of estrogen receptor-alpha in cells of the osteoclastic lineage. Histochem Cell Biol 111: 125-33.	<input type="checkbox"/>
	N	Rosen V et al., (1996) Signaling Pathways in Skeletal Formation: A Role for BMP Receptors. Ann N Y Acad Sci. 785: 59-69	<input type="checkbox"/>
	O	Rosenfeld, M. A. et al. (1992) In Vivo Transfer of the Human Cystic Fibrosis Transmembrane Conductance regulator Gene to the Airway Epithelium. Cell 68:143-155.	<input type="checkbox"/>
	P	Wells, G. et al (2002) V. Meta-Analysis of the Efficacy of Hormone Replacement Therapy in Treating and Preventing Osteoporosis in Postmenopausal Women. Endocrine Reviews 23 (4):529-539.	
	Q	Sato M. et al., (1996) Raloxifene, tamoxifen, nafoxidine, or estrogen effects on reproductive3 and nonreproductive tissues in ovariectomized rates. FASEB Journal. 10(8): 905-912.	<input type="checkbox"/>
	R	Wall, R. J. et al. (1992) Making transgenic livestock: Genetic Engineering on a Large Scale. J. Cell. Biochem. 49: 113-120	<input type="checkbox"/>
	S	Wang EA et al., (1993) Bone Morphogenetic Protein-2 Causes Commitment and Differentiation in C3H10T1/2 and 3T3 Cells. Growth Factors 9:57-71.	<input type="checkbox"/>
	T	Wilson, J. M et al. (1988) Retrovirus-mediated transduction of adult hepatocytes. Proc. Natl. Acad. Sci. USA 85:3014-3018.	<input type="checkbox"/>

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		Application Number	10/642,503
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		First Named Inventor	BODINE, Peter Van Nest
		Group Art Unit	Not yet Known
		Examiner Name	Not yet Known
Sheet	3	of	4
		Attorney Docket Number	P-4921-US

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (where appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	U	Wolff, J. A. et al. (1990) Direct Gene Transfer into Mouse Muscle in Vivo. Science 247:1465-1468.	<input type="checkbox"/>
	V	Wozney JM et al., (1988) Novel Regulators of Bone Formation: Molecular Clones and Activities. Science 242:1528-1534.	<input type="checkbox"/>
	W	Wozney JM et al., (1998) Bone Morphogenetic Protein and Bone Morphogenetic Protein Gene Family in Bone Formation and Repair. Clin Orthop 346:26-37.	<input type="checkbox"/>
	X	Yang NN et al., (1996) Identification of an Estrogen Response Element Activated by Metabolites of 17β-Estradiol and Raloxifene. Science 273:1222-1225.	<input type="checkbox"/>
	Y	Zhou H. et al., (2001) Estrogen Modulates Estrogen Receptor α and β expression, Osteogenic Activity, and Apoptosis in Mesenchymal Stem Cells (MSCs) of Osteoporotic Mice. Journal of Cellular Biochemistry Supplement, 36:144-155 (2001)..	<input type="checkbox"/>
	Z	Wang E et al, (1990) Recombinant human bone morphogenetic protein induces bone formation. Proc Natl Acad Sci U S A. 87(6):2220-4.	<input type="checkbox"/>
	AA	Theis R et al, (1992) Recombinant Human Bone Morphogenetic Protein-2 Induces Osteoblastic Differentiation in W-20-17 Stromal Cells. Endocrinology 130: 1318-24.	<input type="checkbox"/>
	AB	Yamaguchi A (1996) Effects of BMP-2, BMP-4, and BMP-6 on Osteoblastic Differentiation of Bone Marrow-Derived Stromal Cell Lines, ST2 and MC3T3-G2/PA6. Biochem Biophys Research Communications 220: 366-71.	<input type="checkbox"/>
	AC	Moutsatsos (2001) Exogenously Regulated Stem Cell-Mediated Gene Therapy for Bone Regeneration. Mol Therapy 3: 449-61.	<input type="checkbox"/>
	AD	Turgeman G et al, (2001) Engineered human mesenchymal stem cells: a novel platform for skeletal cell mediated gene therapy. J Gene Med 3: 240-51.	<input type="checkbox"/>
	AE	Tissue Culture – Methods and Applications, Academic Press, Kruse & Patterson, editors (1973)	<input type="checkbox"/>
	AF	Paech K et al, (1997) Differential Ligand Activation of Estrogen Receptors Era and Erβ at AP1 Sites. Science 277: 1506-10.	<input type="checkbox"/>
	AG	Yang Y (1996) Estrogen and Raloxifene Stimulate Transforming Growth Factor-β3 Gene Expression in Rat Bone: A Potential Mechanism for Estrogen-or Raloxifene- Mediated Bone Maintenance. Endocrinology 137: 2075-84.	<input type="checkbox"/>
	AH	Ettinger B et al (1999) Reduction of Vertebral Fracture Risk in Postmenopausal Women With Osteoporosis Treated with Raloxifene. JAMA 282: 637-45.	<input type="checkbox"/>
	AI	Nickelsen T et al (1999) Raloxifene hydrochloride, a selective estrogen receptor modulator: safety assessment of effects on cognitive function and mood in postmenopausal women. Psychoneuroendocrinology 24: 115-28.	<input type="checkbox"/>
	AJ	Armentano D et al (1990) Expression of human factor IX in rabbit hepatocytes by retrovirus-mediated gene transfer: Potential for gene therapy of hemophilia B. Proc Natl Acad Sci U S A. 87(16): 6141-5.	<input type="checkbox"/>

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	AK	Ferry N et al (1991) Retroviral-mediated gene transfer into hepatocytes in vivo. Proc Natl Acad Sci U S A. 88(19):8377-81.	<input type="checkbox"/>
	AL	Wilson J et al (1992) A Novel Mechanism for Achieving Transgene Persistence in vivo after somatic Gene Transfer into Hepatocytes. J Biol Chem 267(16):11483-9	<input type="checkbox"/>
	AM	Quantin B et al (1992) Adenovirus as an expression vector in muscle cells in vivo. Proc Natl Acad Sci U S A 89(7):2581-4.	<input type="checkbox"/>
	AN	Dai Y et al (1992) Gene therapy via primary myoblasts: Long-terms expression of factor IX protein following transplatation in vivo. Proc Natl Acad Sci U S A. 89(22):10892-5.	<input type="checkbox"/>
	AO	Van Beusechem et al (1992) Long-term expression of human adenosine deaminase in rhesus monkeys transplanted with retrovirus-infected bone-marrow cells. Proc Natl Acad Sci U S A. 89(16):7640-4.	<input type="checkbox"/>
	AP	Cristiano R et al (1993) Hepatic Gene Therapy: Adenovirus enhancement of receptor-mediated gene delivery and expression in primary hepatocytes. Proc Natl Acad Sci U S A. 90(6):2122-6.	<input type="checkbox"/>
	AQ	Hwu et al (1993) Functional and Molecular Characterization of Tumor-Infiltrating Lymphocytes Transduced with Tumor Necrosis Factor-α cDNA for the Gene Therapy of Cancer in Humans. J Immunology 150: 4104-15.	<input type="checkbox"/>
	AR	Herz J et al (1993) Adenovirus-mediated transfer of low density lipoprotein receptor gene acutely accelerates cholesterol clearance in normal mice. Proc Natl Acad Sci U S A. 90(7):2812-6.	<input type="checkbox"/>
	AS	Clark A et al (1987) Pharmaceuticals from transgenic livestock. TIBTECH Vol. 5, 5: 20-24.	<input type="checkbox"/>
	AT	Hogan B et al (1986) Manipulating the Mouse Embryo, A Laboratory Manual, Cold Spring Harbor, NY, Cold Spring Harbor Laboratory.	<input type="checkbox"/>
	AU	Zhou H et al. (2001) Continuous Parathyroid Hormone and Estrogen Administration Increases Vertebral Cancellous Bone Volume and Cortical Width in the Estrogen-Deficient Rat. Journal of Bone and Mineral Research Vol. 16, No. 7	<input type="checkbox"/>
	AV	Zhou H et al (1993) Estrogens Activate Bone Morphogenetic Protein-2 Gene transcription in Mouse Mesenchymal Stem Cells. Mol Endocrinology 17: 56-66.	<input type="checkbox"/>
	AW	Orly J et al (1994) Tyrosine Kinase Inhibitor AG18 arrests follicle-stimulating Hormone-induced granulosa cell differentiation: Use of reverse transcriptase-polymerase chain reaction assay for multiple messenger ribonucleic acids. Endocrinology 134: 2336-46.	<input type="checkbox"/>
	AX	Feng J et al (1994) Structure and sequence of mouse bone morphogenetic protein-2 gene (BMP-2): Comparison of the structures and promoter regions of BMP-2 and BMP-4 genes. Biochim Biophys Acta 1218: 221-24.	<input type="checkbox"/>
	AY	Heller L et al (1999) Transcriptional Regulation of the Bmp2 Gene. J Biol Chem 274: 1394-1400.	<input type="checkbox"/>
	AZ	Johansson B et al (1994) Evident for Involvement of Activin A and Bone Morphogenetic Protein 4 in Mammalian Mesoderm and Hematopoietic Development. Molecular and Cellular Biology 15: 141-51.	<input type="checkbox"/>
	BA	Garrett I et al, (2001) Statins and Bone Formation. Current Pharmaceutical Design 7: 715-36.	<input type="checkbox"/>

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